UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

NELLCOR PURITAN BENNETT LLC,

Plaintiff,

v.

CAS MEDICAL SYSTEMS, INC.,

Defendant.
_____/

Case No.: 2:11-cv-15697

Honorable Sean F. Cox

OPINION AND ORDER

This case involves claims of false advertising under the Lanham Act and Michigan law.

Plaintiff Nellcor and Defendant CAS Medical Systems Inc. ("CAS") are direct competitors in the manufacture and sale of cerebral oximeters. A cerebral oximeter is a device used by surgeons and anesthesiologists to monitor the oxygen level of blood in the brain. More specifically, cerebral oximeters measure the oxygen saturation level of blood in a region of the brain.

In this case, Nellcor alleges that CAS falsely advertised that its cerebral oximeter is more "accurate" than Nellcor's cerebral oximeter. CAS based its advertising that its cerebral oximeter is more accurate on studies that compared readings from competing cerebral oximeters to an estimate of the average oxygen saturation level of blood in the entire brain called "field saturation" (fSO_2). Although Nellcor raises numerous reasons why CAS's advertising is unreliable and deceptive, Nellcor's principal argument is that CAS's advertising is deceptive because it is based upon using field saturation, which is only a rough estimate of the oxygen saturation level of blood in the entire brain and does not measure the oxygen saturation level of blood in the region of the brain measured by a cerebral oximeter.

The matter is currently before the Court on cross-motions for summary judgment regarding Plaintiff Nellcor Puritan Bennett LLC's ("Nellcor") false advertising claims (Docket Entry Nos. 105

& 109.)

Although the parties have raised numerous issues for summary judgment, the principal issue before the Court is whether it was proper for CAS to advertise that its cerebral oximeter is more accurate than Nellcor's cerebral oximeter based on studies that used field saturation as the correct oxygen saturation level to compare with the readings from the Nellcor and CAS cerebral oximeters.

Nellcor has submitted strong evidence that field saturation is different than regional oxygen saturation and is only in fact an estimate of the average oxygen saturation level of blood in the brain. CAS has also submitted evidence to support its position that field saturation is a sufficiently accurate estimate of regional oxygen saturation when healthy subjects are used in the studies. Although the Court concludes that Nellcor has submitted the stronger evidence, the Court finds that CAS has submitted sufficient evidence to create an issue of fact for trial. Accordingly, the Court will deny the parties' cross-motions for summary judgment as to this issue.

As to the remaining issues in the motion, the Court shall grant in part and deny in part the parties' cross-motions for summary judgment.

Nellcor's Motion for Summary Judgment shall be GRANTED to the extent that the Court rules that CAS has not established facts to support an affirmative defense of res judicata for advertising that occurred after November 11, 2010. It shall be DENIED in all other respects.

CAS's Motion for Summary Judgment shall be GRANTED to the extent that the Court rules that Nellcor has not produced sufficient facts to show that: 1) the Bickler study is unreliable because it only included data for 23 persons; 2) the Bickler study is unreliable because CAS provided draft abstracts for the Bickler study and reviewed the data during the study; 3) the Bickler study is unreliable because CAS provided the cerebral oximeters used in the study and had employees present during the study; 4) the Bickler study is unreliable because cross-talk affected the results of the study; and 5) CAS's "Clinical Corner" web page stating "Summaries of recent studies involving FORE-SIGHT absolute cerebral oximetry" with hyperlinks to ten summaries of studies was material to consumers purchasing decisions. It shall be DENIED in all other respects.

BACKGROUND

A. Background on Cerebral Oximeters

A cerebral oximeter is a device that monitors the oxygen level of blood in the brain by transmitting light into an area of the brain at various wavelengths corresponding to oxygenated and deoxygenated hemoglobin and detecting the light that is reflected. There is a correlation between the oxygen level in the blood and the amount of light that is thereby reflected by the blood. The algorithms used in cerebral oximeters to determine the amount of oxygen in blood in the brain are proprietary to the manufacturers. Surgeons use a cerebral oximeter to monitor for a drop in oxygen level during surgical procedures. If the reading from the cerebral oximeter drops significantly during surgery, then the surgeon will know to take corrective action to prevent permanent injury to the patient.

Cerebral oximeters measure the oxygen level of blood that is located in small vessels in a region of the brain where the light from the cerebral oximeter can penetrate. Cerebral oximeters do not measure the oxygen saturation of blood in the brain as a whole. For this reason, cerebral oximeters are said to measure regional brain oxygen saturation ("rSO_2").

B. Measuring Accuracy of Cerebral Oximeters

This case involves determining whether CAS's cerebral oximeter is more accurate than Nellcor's cerebral oximeter in measuring the oxygen level of blood in a region of the brain.

In order to determine the accuracy of any device, the reading of the device must be compared to the correct value or an accepted reference value. For this reason, the parties agree that accuracy is generally defined as "the closeness of agreement between a test result and an accepted reference value." A useful analogy is to think of a shooter's target having a bullseye. The shots that are on the target are the measured values and the bullseye is the "accepted reference value." The shooters accuracy can be determined based on how close the shots (the measured values) are to the bullseye (the accepted reference value).

Nellcor argues that the bullseye for a cerebral oximeter reading (i.e., the accepted reference

value) is not known so it is impossible to compare the accuracy of competing cerebral oximeters. The best reference value for cerebral oximeter testing would be to take a physical blood sample from the region of the brain that the cerebral oximeter is testing and determine the oxygen level of the sample using proven techniques (called invasive testing). However, the parties agree that it is not possible to take such physical blood samples from the small blood vessels in the region of the brain where a cerebral oximeter takes its readings. Because it is not possible to take physical blood samples from the region of the brain that a cerebral oximeter tests to obtain a reference value, Nellcor argues it is not possible to compare the accuracy of cerebral oximeters.

Historically, because direct calibration and validation of cerebral oximeters was not possible, the first commercially available oximeters were used as "trend monitors," not as absolute monitors which would give the true level of oxygen saturation in the blood. As a trend monitor, before beginning a surgery, a surgeon will read the displayed value on the cerebral oximeter and assume whatever number that is displayed is a healthy level. If during surgery the reading from the cerebral oximeter drops significantly, the surgeon will know to take corrective action.

As time went on, however, some cerebral oximeter manufacturers estimated the true oxygen level of blood in the brain (i.e., the reference value or bullseye) using a surrogate value known as "field saturation," also called "fSO_2." Field saturation is determined by drawing blood simultaneously from two catheters: one placed in the radial artery, such as the forearm, to get an arterial sample (oxygenated blood going to the brain) and one placed in the jugular bulb of the internal jugular vein located at the base of the brain to get a venous sample of blood (blood leaving the brain). The internal jugular vein generally contains blood from a person's entire brain and may include blood from a person's face. However, the higher up in the internal jugular vein a catheter is placed the less likely the sample will contain blood from the face. A catheter placed in the jugular bulb at the base of the brain should not include facial blood. Those blood samples are then placed in a blood gas machine, called a co-oximeter, to determine the oxygen saturation of each sample. It is estimated that brain tissue contains 70-75% venous blood and 25-30% arterial blood. Based on

this principle, field saturation is calculated using a weighted average of the oxygen level from the radial artery and the internal jugular vein. Manufacturers have their own preferences for calculating field saturation: Nellcor uses a 25% arterial blood to 75% venous blood ratio while CAS and another company named Nonin use a 30% arterial to 70% venous ratio. The regional saturation value is then compared to the calculated field saturation value to determine how accurately the device performs.

This main issue in this case is whether it is proper to base comparative advertising on studies that use field saturation data as a reference value to compare with readings from competing cerebral oximeters.

C. Facts and Procedural History

Nellcor and CAS are direct competitors in the manufacture and sale of cerebral oximeters. Nellcor makes the INVOS brand cerebral oximeter; CAS makes the FORE-SIGHT brand cerebral oximeter.

Somanetics, a predecessor to Nellcor, introduced the INVOS cerebral oximeter in 1998.[1] Somanetics had 100% of the market until CAS introduced its FORE-SIGHT cerebral oximeter in 2007. At the present time, Nellcor has approximately 80-85% of the cerebral oximeter market, while the CAS has approximately 10-15%. Another company Nonin has approximately 2-5% of the market.

In 2008, CAS contracted with Duke University to have Assistant Professor of Anesthesiology Dr. David B. MacLeod conduct a study comparing the performance of INVOS and FORE-SIGHT cerebral oximeters. (Pl.'s resp. fact 59.) In order to compare the INVOS and FORE-SIGHT cerebral oximeters, the readings of the oximeters had to be compared to an accepted or correct value. Professor MacLeod used field saturation as the accepted reference value to compare with the readouts from the INVOS and FORE-SIGHT cerebral oximeters. In 2009, Dr. MacLeod published

[1] Somanetics Corporation, which was located in Michigan, made the INVOS cerebral oximeter until being bought by Nellcor in 2010.

the results of his study in two abstracts. In the abstract, Professor MacLeod concluded: "The results demonstrate that the FORE-SIGHT cerebral oximeter monitor has much greater precision with respect to measuring both absolute and trend changes in cerebral tissue oxygen saturation than the INVOS cerebral oximeter monitor." Dr. MacLeod did not conclude that FORE-SIGHT was more accurate than INVOS. Precision relates to how consistent readings from a cerebral oximeter are to each other, while accuracy measures how close readings from the cerebral oximeter are to the correct oxygen saturation level.

On August 7, 2009, Somanetics Corporation, filed a lawsuit against CAS alleging patent infringement and false advertising. (Case No. 09-cv-13110, dkt. no. 35.) In that lawsuit, paragraph 37 of the Complaint stated:

> For example, Defendant stated in an April 21, 2009 press release that a recent study "indicated that FORE-SIGHT absolute cerebral tissue oxygen saturation measurements are three times more accurate than INVOS;" and in an advertisement that appeared in "Neonatal Intensive Care," Vol. 22 No. 4, July-August 2009 touting FORE-SIGHT's use in connection with infants that FORE-SIGHT is "3x more than competitor in absolute terms." These statements are false and/or misleading; the study which purports to support the statement is inherently unreliable , and certainly would not support any claims vis a vis the products' use in connection with infants as the "study" was conducted on a mere nine healthy adults.

In July 2010, Nellcor purchased Somanetics Corporation.

On October 27, 2010, Nellcor and CAS entered into a settlement agreement resolving the patent infringement and false advertising case. On November 11, 2010, the Court entered an "Agreed Order of Dismissal" dismissing all claims and counterclaims with prejudice based on the settlement. (Case No. 09-cv-13110, dkt. no. 56; SMF 156.)

In 2011, CAS contracted with University of California San Francisco to have Professor Bickler conduct a study comparing the accuracy performance of all available cerebral oximeters. The UCSF hypoxia lab is one of the world's leading hypoxia study laboratories. Like the MacLeod study, Professor Bickler also used field saturation as the reference value to compare with readings from the INVOS and FORE-SIGHT cerebral oximeters (i.e., field saturation compared to regional saturation). Using field saturation as the reference value, the data from the Bickler study appears to

conclude through the use of "scatter graphs" that CAS's FORE-SIGHT cerebral oximeter is more accurate than Nellcor's INVOS cerebral oximeter. However, Dr. Bickler only concluded in his poster that "manufacturers should disclose accuracy data for their cerebral oximeter." (CAS s.j. br. at p. 7.)

Based on the MacLeod and Bickler studies, CAS generally advertised and promoted its FORE-SIGHT cerebral oximeter as being more accurate than INVOS.

In May 2011, CAS changed its"Clinical Corner" web page on its web site, adding the heading "Summaries of recent studies involving FORE-SIGHT Absolute Tissue Oximetry," with hyperlinks to ten summaries of studies below it. (SMF 139 and 148.) Three of those summaries discussed studies that had used an INVOS device to collect data, not a FORE-SIGHT device, even though the language of the web page stated that the studies involved a FORE-SIGHT device. Nellcor argues that the inaccurate description on the web site constitutes a separate cause of action for false advertising. The summarized studies each had the basic conclusion that the use of cerebral oximetry may improve patient outcomes. The studies did not compare functionality of INVOS and FORE-SIGHT. Two of the summaries said that an INVOS device that been used in the study to collect data. (SMF 144.) Within two weeks of Nellcor serving the complaint in this case, CAS removed the summaries of the studies and replaced with hyperlinks to the actual studies. The phrase "Summaries of recent studies involving FORE-SIGHT Absolute Tissue Oximetry" was changed to say "Summaries of recent studies involving FORE-SIGHT Absolute Tissue Oximetry and Other NIRS Devices." (SMF 149). CAS states that it changed its web site in an effort to avoid litigation. (SMF 150.)

On December 29, 2011, Nellcor filed the present lawsuit alleging a count for breach of the settlement agreement resolving the 2009 lawsuit and counts for federal and state false advertising, including a violation of the Lanham Act, 15 U.S.C. § 1125(a) (Count II), common law unfair competition (Count III), and trade libel (Count IV). On August 12, 2012, Nellcor filed an amended complaint. (dkt. no. 38.) On June 11, 2013, the Court granted a motion for summary judgment filed

by CAS to dismiss Nellcor's claim for breach of the settlement agreement. Accordingly, only CAS's false advertising claims remain pending in this case.

Presently before the Court are cross-motions for summary judgment filed by Nellcor and CAS as to Nellcor's federal and state false advertising claims. (Dkt. nos. 105 and 109.)

STANDARD OF DECISION

Summary judgment is appropriate only when there is "no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The central inquiry is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 251–52 (1986). Rule 56(a) mandates summary judgment against a party who fails to establish the existence of an element essential to the party's case and on which that party bears the burden of proof at trial. *Celotex Corp. v. Catrett,* 477 U.S. 317, 322–23 (1986).

The moving party bears the initial burden of showing the absence of a genuine issue of material fact. *Celotex,* 477 U.S. at 323. Once the moving party meets this burden, the non-movant must come forward with specific facts showing that there is a genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 587 (1986). In evaluating a motion for summary judgment, the evidence must be viewed in the light most favorable to the non-moving party. *Adickes v. S.H. Kress & Co.,* 398 U.S. 144, 157 (1970).

The non-moving party may not rest upon its mere allegations, however, but rather must set forth specific facts showing that there is a genuine issue for trial. Fed. R. Civ. P. 56(c). The mere existence of a scintilla of evidence in support of the nonmoving party's position will not suffice. Rather, there must be evidence on which the jury could reasonably find for the non-moving party. *Hopson v. DaimlerChrysler Corp.,* 306 F.3d 427, 432 (6th Cir. 2002).

ANALYSIS

The Lanham Trademark Act provides a cause of action for false advertising and provides as follows:

> Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which
>
> > (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,
>
> shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1)(B).

To establish a cause of action for false or misleading advertising under the Lanham Act, the plaintiff must prove the following five elements:

(1) the defendant has made false or misleading statements of fact concerning his product or another's;

(2) the statement actually deceives or tends to deceive a substantial portion of the intended audience;

(3) the statement is material in that it will likely influence the deceived consumer's purchasing decisions;

(4) the advertisements were introduced into interstate commerce; and

(5) there is some causal link between the challenged statements and harm to the plaintiff.

American Council of Certified Podiatric Physicians and Surgeons v. American Board of Podiatric Surgery, Inc., 185 F.3d 606, 613 (6th Cir. 1999) (hereinafter "*Podiatric Physicians"*).

Although a plaintiff may establish a breach of the Lanham Act and thereby be entitled to injunctive relief, additional evidence is required to be entitled to monetary damages in some situations under the Lanham Act. *Id*. at 614. To obtain monetary damages under the Lanham Act for false advertising that is literally true, but misleading, the plaintiff must prove actual deception of consumers. Specifically, the Sixth Circuit has stated:

> When a plaintiff seeks an award of monetary damages for false or misleading advertisement under the Lanham Act, he may show either that the defendant's advertisement is literally false or that it is true yet misleading. Where statements are literally false, a violation may be established without evidence that the statement actually misled consumers. Actual deception is presumed. Where statements are literally true, yet deceptive, or too ambiguous to support a finding of literal falsity, a violation can only be established by proof of actual deception (i.e., evidence that individual consumers perceived the advertisement in a way that misled them about the plaintiff's product). A plaintiff relying upon statements that are literally true yet misleading cannot obtain relief by arguing how consumers could react; it must show how consumers do react. In addition, a Lanham Act claim must be based upon a statement of fact, not opinion.

Id. In other words, "where plaintiffs seek to recover monetary damages for false or misleading advertising that is not literally false, 'a violation can only be established by proof of actual deception (i.e., evidence that individual consumers perceived the advertisement in a way that misled them about the plaintiff's product).'" *Balance Dynamics Corp. v. Schmitt Indus., Inc*., 204 F.3d 683, 690 (6th Cir. 2000) (quoting *Podiatric Physicians*). Under a theory of either literal falsity or true but misleading, the plaintiff must still prove that such harm occurred in order to recover marketplace damages (e.g., damage to goodwill or lost sales). *Id*. at 693-694.

The Sixth Circuit has held that a standard similar to that applicable for injunctive relief is applicable where a plaintiff seeks to recover "damage control expenses," which the Sixth Circuit defines as the costs associated with countering or responding to the defendant's false advertising (e.g., corrective advertising). *Balance Dynamics*, 204 F.3d at 690. Damage control expenses are recoverable upon a showing of likelihood of actual confusion, rather than upon a showing of actual confusion itself. "This rule recognizes that it is unreasonable to expect a businessperson faced with a Lanham Act violation to sit idly by until a customer manifests actual confusion. The law should encourage quick responses and the mitigation of damage, and should not require parties to suffer an injury before trying to prevent it." *Id*. at 691-692.

A. False Advertising Allegations

CAS essentially advertised that "tests prove" its FORE-SIGHT cerebral oximeter is more accurate than Nellcor's INVOS cerebral oximeter. Nellcor argues that CAS's advertising was literally false. This specific type of false advertising claim is referred to as an "establishment claim." For an establishment claim, the plaintiff can prove falsity by evidence that establishes (1) the defendant's test or study was not sufficiently reliable to permit one to conclude with reasonable certainty that it establishes the proposition for which it was cited, or (2) that the test, while sufficiently reliable, does not establish the proposition claimed in defendant's advertising. *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 63 (2d Cir. 1992); *Proctor & Gamble Co. v. Chesebrough-Pond's Inc*., 747 F.2d 114, 119 (2d Cir. 1984). In assessing whether a study or test was reliable, "[t]he fact-finder's judgment should consider all relevant circumstances, including the state of the testing art, the existence and feasibility of superior procedures, the objectivity and skill of the person conducting the tests, the accuracy of their reports, and the results of other pertinent tests." *Proctor & Gamble Co. v. Chesebrough-Pond's Inc,* 747 F.2d at 119.

1. Comparative Accuracy Advertising – Lack of an Accepted Reference Value

Nellcor argues that CAS falsely advertised its FORE-SIGHT cerebral oximeter as being more accurate than Nellcor's INVOS cerebral oximeter because there is not an accepted reference value, or correct oxygen saturation measurement, with which to compare to the readings from the FORE-SIGHT and INVOS cerebral oximeters. According to Nellcor, field saturation is just an estimate or approximation which is not accurate or valid enough to compare the accuracy of competing cerebral oximeters. Without a correct reference value, Nellcor points out that it is impossible to do accurate comparative accuracy testing.

CAS argues that it used the best available reference value for calculating accuracy, field saturation (fSO_2). CAS argues that field saturation is the only available reference value on which to compare readings from the cerebral oximeters. CAS further argues that the United States Food and Drug Administration (FDA) uses and approves the use of field saturation as the reference standard for readings from cerebral oximeters.

In response to CAS's arguments, Nellcor argues that the FDA does not require or use field saturation as a reference value for comparing accuracy of cerebral oximeters. Rather, Nellcor points out that the FDA merely accepts accuracy calculations using field saturation as the reference, and also points out that the FDA does not condone using field saturation for purposes of comparative advertising.

The Court finds that there are factual issues that prevent the Court from granting summary judgment to either Nellcor or CAS. CAS based its superior accuracy claims on studies that compared readings from FORE-SIGHT and INVOS cerebral oximeters with field saturation measurements taken using the arterial/jugular methodology. (CAS's UF 12, *id.*) Field saturation using the arterial/jugular methodology involves taking blood simultaneously from the jugular vein in the neck area at the base of the brain and the radial artery from the forearm area, measuring the oxygen concentrations from the samples using a proven device called a co-oximeter, and then calculating a weighted average of oxygen in the radial artery and jugular vein in ratios of 25-30% arterial 70-75% venous (the exact ratio of depends on individual manufacturer choice). (Nellcor CF ¶¶ 29-30.) To establish its false advertising claim, Nellcor can prove that field saturation is not an accepted or accurate reference value to compare the accuracy of Nellcor and CAS cerebral oximeters. Nellcor has provided clear testimony that the 25-30% arterial blood to 70-75% venous blood ratio is just an estimate and is not necessarily accurate. Nellcor's expert witness testified that the arterial to venous ratio of blood in the brain varies "quite substantially" among individuals and over time within one individual. Specifically, in his deposition, Nellcor's expert witness Dr. Edmonds testified as follows:

> Q. Would you agree that it's a generally accepted principle at this point that the makeup of brain tissue vascularly is about . . . 70 to 75 percent venous and 20 to 25 percent arterial blood?
>
> A. I wouldn't agree to that.
>
> Q. What's your understanding?

> A. My understanding is that it varies. Sometimes it varies quite substantially within – or over time within one individual and perhaps even more so among individuals and that it also varies, not among individuals or within individuals, it varies regionally within regions of the brain.

(Edmonds dep. pgs. 77-78 ll. 11-1.) Thus, because the 75%-25% ratio does not necessarily represent the blood in the brain, Nellcor argues that field saturation is not an accepted reference value. (*See also* Edmonds decl. at ¶ 10.)

Nellcor gives a second reason why field saturation is not an accepted reference value. Even if it is assumed that field saturation is a sufficiently accurate approximation of blood from the entire brain, a cerebral oximeter measures oxygen levels in a region of the brain, not the entire brain. (MacLeod dep. at pgs 28-30 ll. 13-12.) In other words, field saturation and regional saturation measure different things. Field saturation is an estimate or approximation for blood from the entire brain, while a cerebral oximeter measures regional saturation, which is the shallow region of the brain below the sensor of the cerebral oximeters. Oxygen levels in a region of the brain may be different than in other parts of the brain. Nellcor's argument is supported by specific testimony. Specifically, in his declaration and expert report, Nellcor's expert witness Dr. Edmonds testified:

> As explained earlier in my report, the term accuracy generally refers to the closeness of agreement between a measured value (e.g., the value displayed by Nellcor's and CAS's INVOS and FORESIGHT cerebral oximetry products) and an accepted reference value. Thus, claims of superior accuracy as between such devices would, at a minimum, require that there be an accepted reference value against which the values measured by the parties' cerebral oximeters can be compared in order to determine their accuracy. When it comes to cerebral oximetry, however, there are no accepted reference values and no way to test relative accuracy of cerebral oximeters. There is no currently accepted test that can establish that one cerebral oximetry device is more accurate than another.
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> * * *
>
> The oxygenation of blood in the specific areas of the brain being measured by INVOS and FORE-SIGHT can differ significantly from oxygenation of blood in the entire brain. Thus, the value measured by a cerebral oximeter can be accurate, even though it differs greatly from field saturation. As such, any statistic based on closeness of agreement with field saturation does not (and should not) reflect accuracy of a cerebral oximeter.

(Edmonds decl. ¶¶ 6 and 10.)

On the other hand, the Court finds that CAS has submitted evidence to dispute Dr. Edmonds's conclusion that field saturation is not an adequate reference standard. CAS has submitted evidence that in "healthy" persons there is no difference in oxygen levels in different regions of the brain, thereby allowing accuracy testing to be done on healthy persons using field saturation as the reference value. (CAS CF ¶16, dkt. no. 126-127; MacLeod Expert Rep. ¶ 51, ex. H to CAS's SMF, dkt. no. 110-111.) CAS has also submitted evidence that the blood in the brain is approximately 70% venous and 30% arterial. Specifically, CAS's Vice-President of Research and Development, John Gamelin, testified in a declaration:

> As I explained in my deposition, the purpose of conducting accuracy studies on healthy volunteers is that they are unlikely to have any pathological conditions that would make the oxygenation of their brain abnormal, i.e. the blood in their brain is likely to be approximately 70% venous and 30% arterial and that there should not be blood flow abnormalities causing localized differences under the sensor. This allows the researcher to determine whether the cerebral oximeter is accurately determining the amount of deoxygenated and oxygenated hemoglobin in the brain using the vascular blood samples and field saturation values.

(Gamelin decl. ¶ 12, dkt. no. 126-127.)

Although CAS has submitted sufficient evidence to prevent summary judgment, the Court notes that the primary witness relied upon by CAS, Dr. Gamelin, has a Ph.D. in electrical engineering with an emphasis on lasers, not medicine or physiology. The Court assumes that Dr. Gamelin has acquired the relevant knowledge and expertise to testify on matters of physiology and medicine through industry experience. Although the Court will not weigh the credibility of the witnesses at the summary judgment stage of this case, the Court will weigh the evidence and make credibility decisions at trial.

The Court also notes that CAS's expert witness Dr. David MacLeod does not clearly testify that field saturation is an accepted or suitable reference value as a basis for comparative advertising. CAS cites the following quotation from Dr. MacLeod to support its position: "The absence of disease or significant pathology permits the assessment of a device. The comparison of accuracy

performance among several devices using healthy volunteers will yield further useful information to the clinician before the application of the device into the clinical scenario." (MacLeod Decl. ¶ 51, CAS's SMF ex. H(10), dkt. no. 110-111.) However, this quotation merely says that performing accuracy testing on healthy volunteers yields "useful information." At trial, the Court expects CAS to offer clear testimony from Dr. MacLeod to support its position that field saturation is an accepted or suitable reference value for comparative advertising.

The Court also notes that a 2012 publication from CAS's expert witness, Dr. David MacLeod, appears to support Nellcor's argument that field saturation is not an accepted reference value for accuracy comparisons. In his 2012 paper, CAS's expert witness Dr. MacLeod made the following statements:

> "There has been no proven gold standard for determining the absolute or precise level of rSO2 and, therefore, it is impossible to know whether an oximeter-generated rSO2 value agreed absolutely with true cerebral saturation."(Dkt. no. 138, ex. 1 pg. 1007.)

* * *

> "Discussion continues on the ability of any monitor to provide absolute measurement, i.e., whether the value presented absolutely agrees with the true cerebral tissue oxygen saturation. Part of the issue is that there has not been an accepted "gold standard" against which the accuracy of an oximeter could be tested. Over time, however, laboratory data have accumulated showing that cerebral tissue saturation can be estimated using SaO2 and jugular bulb venous saturation (SjvO2) in a ration of 1:3 [by the following equation].
>
> Cerebral arteriovenous saturation [SaO2] = (.25 * SaO2) + (.75 * SjvO2)
>
> This ratio has been used in clinical studies and in validation studies performed in volunteers." (*Id.*)

* * *

> "Validating absolute accuracy has been hampered because there is no established and accepted gold standard for cerebral oximetry and there is no known relation between a particular range of rSO2 values and cellular status. The closest possible clinical estimate of cerebral tissue saturation uses a ratio of 70% venous blood saturation

> (jugular bulb) to 30% arterial blood saturation. Further research is needed to verify that this ratio of arterial-to-venous blood within the cerebral vault represents actual cerebral tissue saturation and to define the parameters of normal versus abnormal cerebral saturation or what value herald potential cerebral injury." (*Id*. at pg. 1011 (emphasis added.))

The last quotation appears to be particularly relevant. Dr. MacLeod states that "further research is needed to verify that this ratio of arterial-to-venous blood within the cerebral vault represents actual cerebral tissue saturation . . ." Thus, as of 2012, Dr. MacLeod believed that further research was needed to confirm that field saturation as calculated accurately represented the true oxygen saturation level of blood in the brain. The Court looks forward to hearing Dr. MacLeod testify at trial on this issue and Nellcor's cross-examination. Based on the evidence above, the Court denies the parties' cross-motions for summary judgment on this issue.

2. Comparative Accuracy Advertising – Reliability of the Bickler and MacLeod Studies

As discussed above, CAS commissioned a study from Dr. MacLeod in 2008 and a study from Dr. Bickler in 2011 to compare the performance and accuracy of cerebral oximeters. In particular, CAS relied upon the results of Dr. Bickler's study to support its advertising that the CAS's FORE-SIGHT cerebral oximeter is more accurate than Nellcor's INVOS cerebral oximeter.

Nellcor argues that the Bickler and MacLeod studies are unreliable and that no reasonable fact-finder could conclude otherwise. In particular, Nellcor argues that CAS designed and manipulated the Bickler study so that the results favored CAS. Nellcor raises a number of problems with how Dr. Bickler collected and analyzed data for his study. Because Dr. Bickler's study is unreliable, Nellcor argues that CAS's advertising was literally false and constitutes false advertising. *See, e.g., Castrol, Inc. v. Quaker State Corp.*, 97 F.2d 57, 63 (2d Cir. 1992).

On the other hand, CAS cross-moves for summary judgment on Nellcor's claim that the MacLeod and Bickler studies are unreliable. CAS argues that even if Nellcor can identify some minor flaws in Dr. Bickler's and Dr. MacLeod's methodologies, none of the alleged flaws is of a

magnitude that the studies are no longer sufficiently reliable. CAS states that the fact that the data from the Bickler abstract is almost identical to the data from the MacLeod study shows that the Bickler study is not flawed.[2] Moreover, the graphs of the data from both studies look very similar. Because the data is almost identical, CAS argues that this is incontrovertible proof that the Bickler study, even if not conducted perfectly, was conducted in a sufficiently reliable manner.

To support its position that Dr. Bickler's study is unreliable, Nellcor raises a number of problems with how Professor Bickler collected and analyzed data for his study. The Court will address Nellcor's principal arguments below.

First, Nellcor argues that Dr. Bickler's study is unreliable because Dr. Bickler performed tests on 33 persons but only included data for 23 of those persons in his paper. Nellcor argues that CAS selected the data that would make its FORE-SIGHT product appear to be the best. Nellcor points to the fact that CAS asked Dr. Bickler to exclude the first five persons and Dr. Bickler agreed to do so. In response, CAS submitted evidence that CAS asked Dr. Bickler to exclude the first five persons tested because one of the cerebral oximeters made by third-party competitor Nonin, the Equanox Advanced, was not present, which would have resulted in the Nonin cerebral oximeter being under represented in the data. (Gamelin decl. ¶ 24 and Ex. 5, located at ex. E to Def.'s SMF, dkt. no. 110-111.) Thus, CAS recommended to Dr. Bickler that he exclude results from those five subjects, which Dr. Bickler agreed to do. (*Id.*) CAS points out that the data for these five subjects still slightly favored FORE-SIGHT as being more accurate (A_{rms} was 6.15 for FORE-SIGHT and 7.02 for INVOS) (a lower A_{rms} means better accuracy). (Kopotic dep. p. 228 ll. 12-17, ex. K to Nellcor mot. s.j.) As to the five other subjects, CAS states that it does not know why Dr. Bickler excluded them from his reported results, but CAS believes that Dr. Bickler excluded those subjects' data because they were obviously incomplete or erroneous, such as when not all devices register a

[2] Dr. MacLeod's data was FORE-SIGHT (-1.59 bias, +/- 3.12 precision) and INVOS (-2.00 bias, +/-9.62 precision). Dr. Bickler's data was FORE-SIGHT (1.73 bias, +/- 3.90 precision); INVOS (.05 bias, +/- 9.72 precision).

reading on a particular subject. (CAS resp. br. at pgs. 9-10, dkt. no. 125.) Based on the evidence provided by CAS and Nellcor, the Court will deny summary judgment to Nellcor and grant summary judgment to CAS as to this issue. The Court finds that Nellcor has not submitted sufficient evidence to show that Professor Bickler designed or manipulated his study to favor CAS.

Second, Nellcor argues that the Bickler study is unreliable because CAS wrote drafts or portions of Dr. Bickler's paper. In response to Nellcor's argument, CAS submitted a declaration from CAS's CEO who testified that although CAS did provide draft abstracts and reviewed data calculations, it was Dr. Bickler's responsibility alone (1) to decide the final content of his abstract and presentation poster about the study; and (2) to ensure that the calculations he presented were correct. (CF ¶ 101; Def.'s SMF ¶¶ 72; Patton May 13, 2013 decl. ¶ 9, located at Ex. H to CF, dkt. no. 127.) Based on the evidence provided by CAS and Nellcor, the Court will deny summary judgment to Nellcor and grant summary judgment to CAS as to this issue. The Court finds that Nellcor has not submitted sufficient evidence to show that the opinions and data in Dr. Bickler's paper were not his own.

Third, Nellcor argues that it should be granted summary judgment as to the reliability of the Bickler study because CAS supplied the cerebral oximeters to be used in the study, including the INVOS device. During the testing, Nellcor argues that CAS employees switched the FORE-SIGHT cerebral oximeter when the original device seemed to not be working properly. Nellcor argues CAS also had its employees present to make sure its equipment was operated properly. Nellcor argues that the study is unreliable because it was not afforded the same opportunity to have employees present during testing. Nellcor states: "Unlike CAS, Nellcor could not verify that the proper model of INVOS was being used, that it was being operated properly, that there was nothing wrong with it, or that CAS did not do something (even unintentionally) to alter INVOS performance." (Nellcor mot. s.j. p. 8.) In response, CAS argues that Nellcor distorts the facts. CAS has submitted testimony that "all devices that were used during the conduct of the Bickler study were functioning properly." (Kopotic decl. ¶ 6, located at ex. D. to Def.'s CF, dkt. no. 126.) CAS submitted

testimony that it only switched devices because the testing was performed over several months and different machines were available at different times. (*Id*. at ¶¶ 4-5.) Moreover, even if it mattered who supplied the cerebral oximeters, CAS submitted a declaration stating that Dr. Bickler supplied the INVOS and Nonin devices, not CAS, for at least one testing session in August 2011. (*Id*. at ¶ 8.) Based on the evidence provided by CAS and Nellcor, the Court will deny summary judgment to Nellcor and grant summary judgment to CAS as to this issue. The Court finds that Nellcor has not submitted sufficient evidence to show that its cerebral oximeter was malfunctioning nor did Nellcor submit sufficient evidence to show that Dr. Bickler's study was unreliable because Nellcor was not invited to have its employees present during testing.

Fourth, Nellcor argues that Dr. Bickler's study is unreliable because there was the possibility of cross-talk, i.e., interference between sensors of different machines, during the Bickler study. Nellcor argues that Dr. Bickler erred in placing sensors from different manufacturers on a subject's forehead at the same time and simultaneously performing tests. Nellcor argues that this procedure can cause the devices to display incorrect measurements because when the devices are run simultaneously, infrared light emitted by one sensor of a cerebral oximeter may interfere with the measurement of a neighboring sensor of a different cerebral oximeter (i.e., "cross-talk"). In response to Nellcor's argument, CAS submitted evidence to support its position that cross-talk did not affect the results of the study. In Dr. Bickler's study, CAS submitted evidence that while some cross-talk was detected on about 10% of the subjects being tested during the setup phase of the cerebral oximeters, Dr. Bickler increased the distance between sensors so that cross-talk did not affect the readings from the cerebral oximeters. (CAS SMF 80-84; CAS CF 112; Kopotic dep. at pgs. 302-303 ll. 6-12 and pgs. 190-191 ll. 1-3, located at ex. J to CAS SMF, dkt. no. 111.) Based on the evidence provided by CAS and Nellcor, the Court will deny summary judgment to Nellcor and grant summary judgment to CAS as to this issue. The Court finds that Nellcor has not submitted sufficient evidence to show that cross-talk affected the readings of Dr. Bickler's study. The undisputed evidence in the record is that Dr. Bickler increased the distance between sensors during the setup phase so that cross-

talk did not affect readings of cerebral oximeters.

Fifth, Nellcor argues that the Bickler study is unreliable because x-rays were not used to confirm that a catheter was properly placed in the internal jugular vein ("IJV"). As discussed above, blood from the IJV is used to calculate field saturation. Because x-rays were not used to confirm placement into the IJV, Nellcor argues that the catheter could have drawn blood from something other than the IJV, or even if in the IJV, the catheter could have been located too low on the IJV such that it drew blood from the face in addition to the brain. Nellcor has submitted declaration and deposition testimony from its expert witness stating that the MacLeod and Bickler studies are unreliable because x-rays were not used to confirm the catheter was properly place in the internal jugular vein. (Edmonds decl. at ¶ 14, ex. Y to Nellcor's SMF in support of s.j., dkt. no. 108; Pl.'s SMF 57-60; Edmonds Dep. 206-211 ll. 15-1., ex. F, dkt. no. 126-127.) In response to Nellcor's argument, CAS "[a]dmits that an improperly placed jugular bulb catheter could affect the blood sampling and therefore affect the statistical results, but disputes that improper placement actually occurred. The record does not support any such inference." (Def.'s CF 59 to Nellcor's mot. s.j., dkt. no. 126; see also CF 57-60.) CAS also admits that a catheter placed too low on the IJV would draw blood from the face in addition blood from the brain. (Def.'s CF 58 to Nellcor's mot. s.j., dkt. no. 126.) However, CAS points out that it is undisputed that Dr. Bickler is a well-respected researcher and doctor, who has been hired in the past by both Nellcor and CAS to conduct clinical studies. According to CAS, it is reasonable to assume that Dr. Bickler is qualified to locate and place a catheter in the IJV of subjects. CAS also argues that one way of confirming the placement of a jugular bulb catheter is to ask the subjects if they are experiencing any facial discomfort. CAS states that this was the methodology used during the Bickler study. (CAS's CF ¶ 115, dkt. no. 126-127.) Based on the evidence provided by CAS and Nellcor, the Court will deny both parties' motions for summary judgment as to this issue. The parties can offer testimony as to this issue at trial. The Court expects both parties to offer testimony from their expert witnesses on how difficult it is for an experienced clinician such as Dr. Bickler and Dr. MacLeod to place a catheter in the IJV so the

Court can assess the reliability of the studies.

Sixth, Nellcor argues that the Bickler and MacLeod studies are unreliable because the studies were conducted on healthy people while cerebral oximeters are normally used by doctors on sick patients. According to Nellcor, the parties' cerebral oximeters may perform differently when used on sick patients. (Nellcor SMF 52-56, dkt. no. 106-108.) In response to Nellcor's arguments, CAS has produced testimony that it is perfectly acceptable to conduct performance testing on healthy patients. (Gamelin decl. ¶ 12, dkt. no. 126-127; MacLeod Expert Rep. ¶ 51.) Based on the evidence submitted, the Court finds that CAS has at the very least created a factual issue to be resolved at trial. Accordingly, the Court will deny the parties' cross-motions for summary judgment as to this issue.

3. CAS's Incorrect Reference To Studies Using Nellcor's INVOS Cerebral Oximeter on its Web Site

Nellcor argues that it is entitled to summary judgment based on a separate instance of false advertising on CAS's web site.

In May 2011, CAS changed its "Clinical Corner" web page on its web site, adding the heading "Summaries of recent studies involving FORE-SIGHT Absolute Tissue Oximetry," with hyperlinks to ten summaries of the studies below it. (Def.'s SMF ¶¶ 139 and 148, dkt. nos. 128-129.) Three of those summaries discussed studies that used an INVOS device to collect data, not a FORE-SIGHT device, even though the heading of the web page stated that the studies involved a FORE-SIGHT device. Nellcor argues that the inaccurate description on the web site constitutes a separate cause of action for false advertising.

The articles and the summaries of the articles on the web site have the basic conclusion that the use of cerebral oximetry may improve patient outcomes. The disputed articles generally relate to the merits of monitoring oxygen and carbon dioxide levels in the brain. The articles do not compare the performances of INVOS and FORE-SIGHT cerebral oximeters and do not analyze the accuracy of the cerebral oximeters. Moreover, two of the summaries on the web site explicitly state that INVOS devices had been used to collect data. (*Id*. at ¶ 144.)

Within two weeks of Nellcor serving the complaint in this case, around the beginning of 2012, CAS changed the heading on its web site from "Summaries of recent studies involving FORE-SIGHT Absolute Tissue Oximetry" to "Summaries of recent studies involving FORE-SIGHT Absolute Tissue Oximetry and Other NIRS Devices." (*Id*. at ¶ 149). CAS also removed the summaries of the studies and replaced them with hyperlinks to the actual studies. (*Id*.) CAS states that it changed its web site in an effort to avoid litigation. (*Id*. at ¶ 150.)

After considering the parties' arguments, the Court will deny Nellcor's motion for summary judgment and grant CAS's motion for summary judgment as to this claim. The disputed studies generally related to the merits of monitoring oxygen and carbon dioxide levels in the brain. To establish false advertising, in addition to proving that the defendant made false or misleading statements of fact, the plaintiff must establish among other things that the statement was material in that it will likely influence the deceived consumer's purchasing decisions and that there is some causal link between the challenged statements and the harm to the plaintiff. *Podiatric Physicians*, 185 F.3d at 613. While the heading of CAS's web site was likely false as to the three studies that involved the INVOS cerebral oximeter, not the FORE-SIGHT cerebral oximeter, given the short amount of time the material was on the web site and the fact that articles only generally relate to cerebral oximetry, the Court finds that a reasonable fact-finder would not find the web page to be material in affecting a consumer's purchasing decision or caused Nellcor harm. The allegedly false descriptions were on the CAS's web site for less than a year and the studies did not involve comparative advertising, but were rather in the natural of general background information about cerebral oximetry.

B. The Sufficiency of Nellcor's Complaint

CAS argues that the Court should deny Nellcor's motion for summary judgment because Nellcor advances theories of liability that are not alleged in its Amended Complaint.

Nellcor filed its Amended Complaint in August 2012. (Dkt. no. 38.) Count II of the Amended Complaint generally alleges a claim for false advertising under the Lanham Act and gives

three specific examples of false advertising: (1) the use of the phrase "Summaries of recent studies involving Fore-Sight Tissue Oximetry" on a web page was false because some of the studies listed below it involved INVOS; (2) a summary of a study titled "Preoperative Cerebral Oxygen Saturation and Clinical Outcomes in Cardiac Surgery; (3) an October 27, 2011 press release, claiming that FORE-SIGHT is more accurate than INVOS based on the Bickler study "at least because the standard deviation values determined during the study are not indicative of accuracy." (Am. compl. ¶¶ 28-30.)

CAS argues that Nellcor's Amended Complaint is deficient because it now asserts the following additional theories:

- "All statements by CAS about superior accuracy are false because the accuracy of a cerebral oximeter cannot be determined, *see, e.g.*, Plf.'s Br. pp. 4-6 ll. 14-16;"
- "All statements by CAS about accuracy based on the MacLeod and Bickler studies are false because both studies were conducted in an unreliable manner, *Id*. pp. 6-10 ll. 14-16;"
- "All statements by CAS about accuracy based on the MacLeod and Bickler studies are false because they were conducted on healthy volunteers, but cerebral oximeters are used on sick patients, *Id*. p. 10; and"
- "All statements by CAS that studies involve or validate Fore-Sight are false if the study had data collected with an INVOS, *Id*. p. 11."

It appears to the Court that Nellcor's principal theories were at least disclosed to CAS in expert reports and depositions, especially in the expert report and deposition testimony of Nellcor's expert witness Harvey Edmonds. The Court finds that CAS has not shown that it has been surprised and prejudiced by the fact that Nellcor failed to amend its complaint to clearly articulate all of its legal theories. However, the Court does agree with CAS that Nellcor did not amend its pleadings to clearly articulate all of its legal theories and that CAS should not be prejudiced by Nellcor's failure to amend its pleadings. This Court expects litigants to conduct themselves according to the Federal Rules of Civil Procedure and the Local Rules of the United States District Court for the

Eastern District of Michigan. The Court feels that this case is ready for trial, principally on the issue of whether field saturation is an acceptable reference for conducting comparative advertising of cerebral oximeters. This issue will be further discussed at the final pretrial conference. Through the Court's final pretrial order, the Court will limit the trial to those theories timely and adequately raised.

C. *Res Judicata*

CAS argues that Nellcor's false advertising claims are barred in whole or part by the doctrine of res judicata, especially advertising relying on the MacLeod study, because Nellcor filed and dismissed with prejudice a similar false advertising case between 2009-2010.

On August 7, 2009, Nellcor (then Somanetics Corporation) filed a lawsuit against CAS alleging patent infringement and false advertising. (Case No. 09-cv-13110, dkt. no. 35.) In that lawsuit, paragraph 37 of the Complaint stated:

> For example, Defendant stated in an April 21, 2009 press release that a recent study "indicated that FORE-SIGHT absolute cerebral tissue oxygen saturation measurements are three times more accurate than INVOS;" and in an advertisement that appeared in "Neonatal Intensive Care," Vol. 22 No. 4, July-August 2009 touting FORE-SIGHT's use in connection with infants that FORE-SIGHT is "3x more accurate than competitor in absolute terms." These statements are false and/or misleading; the study which purports to support the statement is inherently unreliable, and certainly would not support any claims vis a vis the products' use in connection with infants as the "study" was conducted on a mere nine healthy adults.

On October 27, 2010, Nellcor and CAS entered into a settlement agreement resolving the prior patent infringement and false advertising case. On November 11, 2010, the Court entered an "Agreed Order of Dismissal" dismissing all claims and counterclaims with prejudice based on the settlement. (Case No. 09-cv-13110, dkt. no. 56; Def.'s SMF 156 and Pl.'s CF 156.)

The doctrine of *res judicata* (claim preclusion) provides that a final judgment on the merits of an action precludes the parties or their privies from relitigating issues that were or could have been raised in a prior action." *In re Alfes*, 709 F.3d 631, 638 (6th Cir. 2013) (quotations omitted). "Res judicata refers to the effect of a judgment in foreclosing litigation of a matter that never has been litigated, because of a determination that it should have been advanced in an earlier suit." *Migra v.*

Warren City Sch. Dist. Bd. of Educ., 465 U.S. 75, 77 n.1 (1984). The Sixth Circuit has held that res judicata should be employed when the following four elements are satisfied:

> (1) a final decision on the merits by a court of competent jurisdiction; (2) a subsequent action between the parties or their privies; (3) an issue in the subsequent action which was litigated or which should have been litigated in the prior action; and (4) an identity of the causes of action.

In re Alfes, 709 F.3d at 638.

"[R]es judicata applies to both claims actually raised in the prior action and to every claim arising out of the same transaction which the parties, exercising reasonable diligence, could have raised but did not." *Ziba v. Kcira*, 2010 WL 4636635 (E.D. Mich. 2010) (Cox, J.).

CAS argues that Nellcor's claims in this case involve the same issues as the previous case from 2009-2010 and are therefore barred by the doctrine of res judicata. In response to CAS's arguments, Nellcor argues that its claims are based on advertising that occurred subsequent to the dismissal of the previous case in 2010 and are therefore not barred by the doctrine of res judicata. Nellcor also points out that it is not alleging that the MacLeod study or abstract contains false information. In fact, Nellcor points out that Dr. MacLeod's 2009 abstract does not conclude that the INVOS cerebral oximeter is more "accurate" than the FORE-SIGHT cerebral oximeter, but rather contains data related to "bias" and "precision" of the cerebral oximeters using field saturation as the reference value. Accuracy is a different concept than bias and precision. Rather, Nellcor states that it is alleging that CAS's advertising and statements subsequent to the dismissal of the previous lawsuit constitute false advertising.

The Court agrees with Nellcor and holds that claims involving advertising that occurred subsequent to the dismissal of the prior lawsuit in 2010 are not barred by the doctrine of res judicata. More specifically, the Court finds that the fourth element of res judicata, "an identity of the causes of action," is not satisfied for alleged false advertising that occurred subject to the dismissal of the previous lawsuit in 2010.

The Court finds the present case to be similar to the case of *Ziba v. Kcira*, 2010 WL 4636635 (E.D. Mich. 2010) (Cox, J.). In that case, Ziba, a wedding photographer, alleged that Kcira, a priest

at an Albanian Catholic church, told his congregation that Ziba was not allowed in St. Paul's Albanian Parish because he was a Muslim terrorist and a Taliban. Moreover, Ziba alleged that Kcira told the congregation that he would not marry anyone who hired Ziba to videotape/photograph their wedding. Ziba sued alleging defamation and other causes of action. The parties settled the case with a simple order that stated the matter was "dismissed with prejudice," although the settlement agreement between the parties provided inter alia that (1) the Archdiocese of Detroit would pay Ziba's attorney $5,200; (2) the Archdiocese of Detroit would make a statement on Albanian television or radio that Mr. Ziba is allowed to work for parishioners of St. Paul; and (3) Ziba would sign a document agreeing to abide by the parish's rules. After the settlement and dismissal, Kcira allegedly continued to call Ziba a Taliban and/or Muslim terrorist. Ziba filed a new lawsuit for the continued defamation. Kcira filed a motion for summary judgment arguing that res judicata barred Ziba's claims because the same claims were previously alleged and settled through a dismissal with prejudice. The Court held that res judicata did not apply because the continued defamatory statements were separate torts that occurred after the dismissal of the previous case.

Similar to *Ziba v. Kcira*, the Court finds that CAS's advertising that occurred subsequent to the dismissal of the previous lawsuit in 2010 would be separate torts and therefore are not barred by res judicata. Accordingly, the Court will deny CAS's motion for summary on this issue and grant Nellcor's motion for summary judgment on this issue.

D. Causation For Lost Sale Damages

Defendant CAS argues that it is entitled to summary judgment as to the issue of damages for lost profits because Nellcor has not submitted sufficient evidence to show that CAS's advertising and promotion caused Nellcor to lose sales and thereby lost profits. Citing to *Bracco Diagnostics, Inc. v. Amersham Health. Inc*., 627 F. Supp. 2d 384 (D. N.J. 2009), CAS argues that Nellcor must prove that CAS's actions were a "material" or "substantial" cause of its injury. CAS argues that cerebral oximeters are sold to sophisticated buyers who do not make purchasing decisions based on marketing and advertising claims, but rather base their purchasing decisions by testing and

evaluating the competing product in the field prior to purchase. (CAS's CF 78 to Nellcor s.j. mot., dkt. no. 126-127.)

In response to CAS's cross-motion for summary judgment on this issue, Nellcor has submitted evidence to support causation. Citing to *Balance Dynamics Corp. v. Schmitt Indus., Inc*., 204 F.3d 683, 689 (6th Cir. 2000), Nellcor also argues that under Sixth Circuit law it only needs to prove "*some causal link* between the challenged statements and the harm to the plaintiffs." *Id*. at 689 (emphasis added).

Taking the evidence in the light most favorable to the non-movant Nellcor, the Court finds that Nellcor has submitted enough circumstantial evidence to support its position that CAS's alleged false advertising has caused Nellcor to lose sales. Somanetics had 100% of the market for cerebral oximeters until CAS introduced its FORE-SIGHT cerebral oximeter in 2007. At the present time, Nellcor has approximately 80-85% of the cerebral oximeter market, while the CAS has approximately 10-15%. Another company Nonin has approximately 2-5% of the market. Nellcor and CAS compete head-to-head and CAS is actively targeting Nellcor's customers. (Baird dep. at p. 62-63 ll. 21-15, located at ex. W to Nellcor SMF, dkt. no. 106-08; CAS's CF 74-75, dkt. no. 126-127.) Nellcor submitted evidence that CAS's marketing and sales strategy is to gain market share and get the attention of doctors and hospitals by stating that its FORE-SIGHT cerebral oximeter is more accurate than its competitors, including INVOS cerebral oximeter. It did this by *inter alia* having its sales force distribute and rely upon summaries of studies saying that FORE-SIGHT is more accurate than INVOS, including on its web site. (Herwig dep., located at ex. V to Nellcor's SMF, dkt. no. 106-08; *see also* CAS's CF 66-68, dkt. no. 126-127.)

For example, Nellcor submitted the following testimony from CAS's Director of Research and Development John Gamelin:

> Q. Is your statement here indicating that you think the distinguishing factor between FORE-SIGHT and other cerebral oximeters is the degree of accuracy?
>
> A. Yes.

Q. And when we talk about the distinguishing factor, you mean to customers and potential customers, correct?

A. That would be my understanding, yes.

(Gamelin dep. at p. 179 ll. 7-16, ex. W to Nellcor's mot. s.j., dkt. no. 126-27.)

Nellcor also submitted the deposition testimony from CAS's Chief Financial Offer who stated that CAS wins accounts by telling customers that FORE-SIGHT is more accurate than INVOS. Specifically, CAS's CFO testified as follows:

Q. And when CAS Medical wins an account from INVOS, does CAS medical do that by telling customers that the FORE-SIGHT is more accurate than the INVOS product?

Mr. DOROGHAZI: Object. Not designated on this topic, and I'll just put a continuing objection in, so . . .

MS. CROWSON: Sure

Q. You're giving your personal understanding?

A. Yeah, I don't think there's any – we're proud of the fact that the technology is better.

Q. So you're saying the answer to my question is yes?

A. Yes.

(Baird dep. P. 65 ll. 4-21, *id*.) While CAS argues that Mr. Baird, CAS's CFO, is not involved in sales and marketing, CAS has admitted that it submits information about clinical studies to customers in order to garner interest in FORE-SIGHT so that the consumer will engage in a clinical evaluation process and eventually purchase FORE-SIGHT. (CAS's CF 66, dkt. no. 126-127.)

Taking the evidence in the light most favorable to Nellcor the non-movant, the Court holds that there is enough evidence to create an issue of fact for trial. Accordingly, the Court denies CAS's motion for summary on the issue of causation of lost sales.

E. Nellcor's Claim For Corrective Advertising Damages

As part of its false advertising claim, Nellcor is seeking money to conduct a prospective marketing campaign to counteract CAS's alleged false advertising and promotion of its FORE-SIGHT cerebral oximeter as being more accurate than the INVOS cerebral oximeter. This type of

damages claim is sometimes called corrective advertising.

CAS has moved for summary judgment on Nellcor's claim of corrective advertising. CAS argues that in order to recover corrective advertising damages the plaintiff must have timely engaged in corrective advertising to counteract the harm at the time of the false advertising unless it was financially incapable of such corrective advertising. As authority for its argument, CAS relies upon on *Kargo Global, Inc. v. Advance Magazine Publishers, Inc.*, 2007 WL 2258688 (S.D.N.Y. 2007).

The Sixth Circuit has not directly addressed this issue.

At least one circuit court, the Ninth Circuit, does not follow the requirement that a plaintiff must timely engage in corrective advertising at around the time of the false advertising in order to recover corrective advertising. *See Adray v. Adry-Mart, Inc.*, 76 F.3d 984, 988 (9th Cir. 1995).

Without much analysis, both sides argue that the Sixth Circuit case of *Balance Dynamics Corp. v. Schmitt Indus., Inc*., 204 F.3d 683 (6th Cir. 2000) supports its position.

Balance Dynamics did not involve a request for money for "prospective" corrective advertising. To the contrary, the plaintiff in *Balance Dynamics* sought to recover money it had already spent on corrective damages around the time of the false advertising in order to prevent lost sales. Moreover, the plaintiff admitted that the false advertising did not result in lost sales or other actual damages. Based on these facts, the Sixth Circuit held that the plaintiff could recover its past corrective advertising expenses even though the plaintiff did not lose any sales and could not prove it was otherwise damaged. The court reasoned that "[d]amage control expenses must be treated differently from marketplace damages because, like an injunction, damage control is undertaken precisely to prevent such things as lost sales, lost profits, and lost goodwill." *Id*. at 691. "This rule recognizes that it is unreasonable to expect a businessperson faced with a Lanham Act violation to sit idly by until a customer manifests actual confusion. The law should encourage quick responses and the mitigation of damage, and should not require parties to suffer an injury before trying to prevent it." *Id*. at 691-692. In other words, the Sixth Circuit reasoned that a plaintiff should be not penalized for incurring damage control costs in an effort to mitigate or prevent actual damages. *Id*.

at 692.

After considering the parties' arguments, the Court agrees with Nellcor and denies CAS's motion for summary judgment as to this issue. It is the Court's understanding that Nellcor is seeking to obtain the amount of money necessary to conduct a corrective advertising campaign to counteract the effects of CAS's alleged false advertising as part of its actual damages (e.g., damages to goodwill). As in any case, Nellcor is entitled to recover the amount of money necessary to engage in a corrective advertising campaign to correct for any damage to Nellcor's goodwill proved to be caused by CAS's false advertising. The Ninth Circuit came to the same conclusion in *Adray v. Adry-Mart, Inc*., 76 F.3d 984, 988-89 (9th Cir. 1995). The Ninth Circuit held that a plaintiff may obtain costs to conduct a corrective advertising campaign to dispel the confusion caused by the defendant. *Id*. Like *Adray v. Adry-Mart*, if Nellcor is successful on its false advertising claim and establishes that its goodwill has been harmed, Nellcor is entitled to obtain the amount of money reasonably necessary to conduct a corrective advertising campaign to counteract the effects of CAS's false advertising.

F. State-Law Claims

Nellcor's Amended Complaint contains counts for common law unfair competition and trade libel under Michigan law. It is the Court's understanding that these claims raise the same principal issues, including whether CAS's advertising was false or deceptive in asserting that CAS's cerebral oximeter is more accurate than Nellcor's cerebral oximeter. The Court's reasoning and decisions above will also apply to Nellcor's state law claims.

CONCLUSION & ORDER

As set forth above, IT IS ORDERED that the Court GRANTS IN PART and DENIES IN PART the parties' cross-motions for summary judgment.

Nellcor's Motion for Summary Judgment is GRANTED to the extent that the Court rules that CAS has not established facts to support an affirmative defense of res judicata for advertising that occurred after November 11, 2010. It is DENIED in all other respects.

CAS's Motion for Summary Judgment is GRANTED to the extent that the Court rules that Nellcor has not produced sufficient facts to show that: 1) the Bickler study is unreliable because it only included data for 23 persons; 2) the Bickler study is unreliable because CAS provided draft abstracts for the Bickler study and reviewed the data during the study; 3) the Bickler study is unreliable because CAS provided the cerebral oximeters used in the study and had employees present during the study; 4) the Bickler study is unreliable because cross-talk affected the results of the study; and 5) CAS's "Clinical Corner" web page stating "Summaries of recent studies involving FORE-SIGHT absolute cerebral oximetry" with hyperlinks to ten summaries of studies was material to consumers purchasing decisions. It is DENIED in all other respects.

IT IS FURTHER ORDERED that the Court will schedule a final pretrial conference in the near future and then set a trial date.

IT SO ORDERED

S/Sean F. Cox
Sean F. Cox
United States District Judge

Dated: March 28, 2014

I hereby certify that a copy of the foregoing document was served upon counsel of record on March 28, 2014, by electronic and/or ordinary mail.

S/Jennifer McCoy
Case Manager